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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,101	09/10/2003	Richard R. Bott	DOC 0056 IA/40218.130/DC5	6874

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,101	BOTT ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 5/16/06 to claims 56-61, 66, and 67 have been entered. Claim 72 has been added. Claims 56-72 remain pending in the current application, all of which have been considered on the merits.

Prior art references can be found in a prior Office action, unless otherwise noted.

Claim Objections

The objection to claim 67 is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 57, 66, and 67 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement are withdrawn in light of the claim amendments and applicant's comments.

Claims 59-61 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988); these factors can be found above.

The cited claims have been interpreted as being broadly drawn to a method comprising placing a topical preparation comprising a protein or enzyme in contact with the skin of a patient, such that the active agent is released onto said skin, thus sterilizing a wound on the skin, preventing infection of the skin, and accelerating healing of a wound on the skin, respectively, for purposes of this rejection only.

As discussed above, the claims are problematic in that the person of ordinary skill in the art would not have a reasonable expectation that any given active agent would sterilize a wound, prevent infection, and/or accelerate wound healing, even if applied directly to the affected skin. The person of ordinary skill in the art would not have a reasonable expectation that any given enzyme would have any of the outcomes recited in claims 59-61. For example, glucokinase is certainly an enzyme, but the skilled artisan would have no reason to expect that glucokinase would sterilize a wound, prevent infection, and/or accelerate wound healing, since it is a metabolic enzyme.

Furthermore, as discussed above, the working embodiment is narrow and does not address all of the outcomes in claims 59-61. As discussed above, the specification presents a narrow working embodiment in which eschar is soaked in a few solutions of proteases (Examples 11-14). At no point is a composition in accordance with the claims applied to skin and a wound being sterilized thereby; anti-infection properties imparted thereby; or wound healing accelerated thereby. In fact, the specification does not

address these requirements at all, much less provide sufficient guidance to use the claimed method for the outcomes of claims 59-61. The specification provides no guidance for selecting an enzyme that would sterilize a wound, provide anti-infection properties, and/or accelerate wound healing. In short, the specification as filed is insufficient to support these claims.

While a narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

Applicants urge that the specification provides "an extensive list of known proteins and enzymes having known properties that would result in wound sterilization, infection prevention, or accelerated healing" (Reply, page 8, paragraph 3). Applicants further allege, "One skilled in this art would have an understanding of which of the many listed proteins and enzymes would have the properties needed to provide the recited functions" (Reply, page 9, paragraph 1). These arguments have been fully considered, but they are not persuasive.

While the specification does recite numerous enzymes that are suitable for incorporation into the composition provided in the cited claims (as-filed specification, page 12, line 7, through page 15, line 8, "pages 12-15"), the disclosure also emphasizes that this list is not exhaustive. (The examiner also notes for the record that the list of "known proteins and enzymes" in the specification comprises only enzymes, no other

type of protein.) At page 15, lines 5-6, the specification recites, "It will be understood by those having skill in the art that the present invention is not limited to the enzymes listed [at pages 12-15]." At page 12, line 22, the specification allows that the enzyme may be any that "show a positive immunological cross-reaction with the antibody of [*Pseudomonas fluorescens* IAM 1057]," a definition that encompasses enzymes and proteins that have not yet been discovered by applicant or others. At page 13, line 17, the specification includes among appropriate enzymes "close structural enzyme variants" of proteases produced by any organism, a definition that could be interpreted to encompass any protein that has some similarity of some undefined type and to some undefined extent to any protease. At page 14, lines 3-12, the specification includes within the list of proteases any enzymes that are modified in any way at particular positions relative to another enzyme. Clearly, the specification's intent was to prevent from exclusion any enzyme that might be one day discovered to have the claimed properties, which is not the standard for enablement.

Even if the limitation "protein or enzyme" in claim 56 were interpreted as being limited to those at pages 12-15, the specification does not provide sufficient guidance that the skilled artisan could select proteins or enzymes without undue experimentation that impart the claimed properties when a composition is administered as claimed. The specification discusses these enzymes in terms of their **possible** appropriateness for inclusion in compositions such as are applied to skin in the instant claims, not in terms of any reasonable probability that any of these enzymes would be appropriate. For example, at page 12, line 17, the specification discusses "[l]ipase enzymes **which may**

be considered to be suitable for inclusion..." while page 13, lines 21-22 recites similar language applied to proteases. The specification provides no correlation between particular enzyme activities or protein properties and a reasonable expectation of the properties recited in the cited claims.

As pointed out in the rejection in the first Office action, there are numerous proteins and enzymes (including glucokinase and other metabolic enzymes) that would not reasonably be expected (without undue experimentation) to provide the effects recited in claims 59-61. The specification provides no guidance, except trial and error, for identifying proteins or enzymes from the billions of possible proteins or enzymes in existence that would provide the claimed outcomes. In light of the unpredictable nature of the art and the limited scope of the working examples (which, again, are drawn solely to the action of a few proteases), the skilled artisan would not have had a reasonable expectation of success in using the claimed method with the claimed outcomes without undue experimentation.

Claims 57-61, 66, 67, and 72 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 recites, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such

descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

In this case, the claims are broadly drawn to methods comprising applying to skin compositions comprising various proteins or enzymes that may have various effects. Claims 67 and 72 also recite a second active agent that inhibits the protein or enzyme. The specification, however, provides no criteria by which proteins or enzymes that have the properties in claims 57-61, 66, 67, and 72 might be selected without extensive experimentation. Likewise, no criteria are provided for selecting an effective inhibitor for a protein or enzyme.

M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus...when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. **For inventions in an unpredictable art,**

adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus."

The specification implies that virtually any enzyme, from any source, having any activity, is contemplated by the invention (specification, pages 12-15). At no point, however, does the applicant provide any evidence toward a reasonable expectation that a given enzyme from pages 12-15 would have any of the activities recited in claims 57-61 and 66 or any guidance for choosing an enzyme from this list that has the desired activity. As discussed above, applicant's examples show that a few proteases have some effect on eschar *in vitro* (protease B subtilisin, *C. histolyticum* collagenase, and protease from *B. subtilis* LG12; Examples 11-14). At no point are the activities of claims 57-61 and 66 correlated with the enzymes listed at pages 12-15. The person of ordinary skill in the art would not immediately envisage the structures and sequences of the enzymes having the claimed properties from the information provided and the knowledge in the prior art.

Likewise, claims 67 and 72 recite the inclusion of "at least one second active agent selected such [that] said second active agent inhibits said [first] active agent," but the specification provides no guidance for identifying an inhibitor for every enzyme listed at pages 12-15. At page 19, line 21, through page 20, line 7, the specification suggests the inclusion of a second active agent and provides a few examples for potential inhibitors of a few proteases, but no guidance is provided for the selection of an inhibitor of, for example, any given pectinase (one of the enzymes contemplated for use in the

invention; page 12, line 13). The specification does not provide any criteria that link the function of said inhibitor with a given structure or sequence.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. Written description" requirement may be satisfied by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that **fully set forth** the claimed invention. See *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) and *Lockwood v. American Airlines, Inc.*, 107 F.3d at 1572, 41 USPQ2d at 1966. A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3 at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997). See also *Fiers v. Ravel*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (Fed. Clarification is required. 1993) (discussing *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). See M.P.E.P. § 2163.

In this case, the active agents and inhibitors are claimed and described only by their activities, not by structural or sequence limitations that would correlate a given active agent to a given activity and a given inhibitor to a given active agent. As such, the requirement for written description of biomolecules has not been fulfilled.

Applicants again urge that the specification provides a list of known proteins and enzymes that are suitable for controlled release as in the claimed methods (Reply, page 9, paragraph 3). Applicants allege that since their claims are drawn to methods of using biomolecules, rather than to biomolecules *per se*, that the claims are adequately described (Reply, page 9, paragraph 4). These arguments have been fully considered, but they are not persuasive.

As discussed above, the list of "proteins and enzymes" is in essence a list of every existing enzyme, and no correlation between any particular structure (*i.e.* protein sequence) and function (*i.e.* the outcomes recited in the cited claims) is provided. The claims, therefore, are drawn to a method comprising applying a composition that comprises some undefined enzyme with a particular activity to be determined by future experimentation. While the claims are not drawn to biomolecules *per se*, it is established that methods of using inadequately described compounds are themselves inadequately described. The court's decision in *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003), illustrates these principles.

Whether a few enzymes with the claimed properties are known in the art is not the issue; the cited claims are drawn to methods comprising administering any protein or enzyme with particular activities, including those known and those yet to be identified. Applicant provides no guidance for identifying additional such proteins or enzymes except by trial-and-error screening, as implied at pages 12-15. The cited claims are drawn in part to a method for sterilizing a wound, providing anti-infective properties, and

accelerating wound healing comprising administering an unspecified compound to patients.

In *University of Rochester*, at issue was a patent directed to method for inhibiting prostaglandin (PGHS-2) synthesis in a patient using an unspecified compound. The District Court of Western New York evaluated the level of disclosure required to satisfy the written description. In their decision (which was later affirmed by the CAFC), the District Court wrote, "The real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process."

The patent in *Rochester* does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. The specification of the patent in *Rochester* states that the invention comprises, inter alia, "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds." Nowhere, however, does it specify which "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.

The *Rochester* court cited the CAFC in *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 296 F.3d 1316 (63 USPQ2d 1609), which adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics *when coupled with a known or disclosed correlation between function and structure* ... ." *Enzo*, 296 F.3d at 1324-25 (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)).

The *Rochester* court cited the CAFC in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 [43 USPQ2d 1398] (Fed. Cir. 1997), in which the court drew a distinction between genetic material and other chemicals; in drawing this distinction, however, the court also stated that "[i]n claims involving [non-genetic] chemical materials, generic formulae *usually indicate with specificity what the generic claims encompass.* One skilled in the art can distinguish such a formula from others and *can identify many of the species* that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." 119 F.3d at 1568 (emphasis added). There is no such specificity here, nor could one skilled in the art identify any particular compound encompassed by the claims. To the contrary, the specification states that suitable compounds might be found from among an array of organic and inorganic materials.

The fact pattern in this case is similar to that in *Rochester*. In *Rochester*, there were no compounds known to have the required function, while in the instant application, a diverse and exhaustive list (pages 12-15 encompass essentially every enzyme in existence) is disclosed. The key similarity between the cases, and the one relevant to this ground of rejection, is the fact that no method (other than trial-and-error) is provided for identifying compounds having the desired functions. For this reason, the rejection due to lack of written description is proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejections of record under 35 U.S.C. § 112, second paragraph, are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 102

The rejections under 35 U.S.C. § 102 are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 56, 62-65, and 68-71 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (U.S. Patent 6,060,546). The claims are interpreted as being drawn to a method of providing an active agent comprising a protein or enzyme

topically, said method comprising providing a topical preparation comprising an internal phase and an external phase, wherein the internal phase is dispersed within the external phase; the internal phase comprises at least one hydrophilic carrier and at least one protein or enzyme; and the external phase comprises a silicone matrix; and placing said preparation in contact with the skin of a patient such that said protein or enzyme is released from said matrix topically onto said skin. In some dependent claims, the composition has particular physical properties (62-65). In some dependent claims, the carrier is propylene glycol (68). In some dependent claims, the active agent is particularly pointed out (69-71).

As discussed previously, Powell et al. teach silicone emulsions comprising a silicone phase and an organic phase, wherein the silicone phase comprises a cross-linked silicone elastomer and the organic phase is dispersed within the silicone phase (Abstract; column 3, lines 13-16). Powell et al. teach that the organic liquid in the organic phase is preferably a C1-C12 alcohol, such as polypropylene glycol and other propylene glycols (column 15, lines 54-67). Powell et al. teach that the organic phase may comprise a protease (column 17, lines 1-5). Powell et al. also teach applying the emulsions to the skin (Example 12).

Powell et al. do not teach modifying the composition so as to change active agent release rates, as recited in claims 62-65. Powell et al. do not teach a composition comprising the specific protease LG12.

The selection of cross-link density, thickness, and occlusivity to air of the composition of Powell et al. would have been a routine matter of optimization on the

part of the artisan of ordinary skill, said artisan recognizing that Powell et al. teach that the density of crosslinking is easily varied (Example 3), that the thickness of the composition would be varied depending on the size of the active agent and desired rate of release, and that the occlusivity to air varies with thickness and degree of cross-linking. A holding of obviousness over the cited claims is therefore clearly required.

The selection of hydrophilic component would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Powell et al. teach that the hydrophilic component may be polypropylene glycol (column 15, line 67). A holding of obviousness over the cited claims is therefore clearly required.

The selection of protein or enzyme would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the enzyme may be selected depending on the desired activity of the composition. A holding of obviousness over the cited claims is therefore clearly required.

A person of ordinary skill in the art would have had a reasonable expectation of success in modifying the composition of Powell et al. and applying the same to skinas discussed above because Powell teaches optimizing the composition for desired downstream applications. The skilled artisan would have been motivated to vary the degree of cross-linking, thickness of the composition, occlusivity to air, hydrophilic component, and active agent depending on the condition to be treated.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the composition of Powell et al. as above and to apply it to the skin because the prior art itself suggests such modifications.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that Powell et al. "is directed to a non-aqueous emulsion in which the organic liquid forms an internal phase in the continuous silicone phase" (Remarks, page 13, paragraph 2, and page 14, paragraph 2). Applicant further alleges that Powell et al. do not teach or suggest a three-component internal phase (*ibid.*). These arguments have been fully considered, but they are not persuasive.

While Powell et al. term their emulsion as comprising an "organic phase" and a "silicone phase," the "organic phase" is preferably an alcohol, such as polypropylene glycol (which applicant defines as a "hydrophilic carrier," claim 68). Clearly, Powell et al. contemplate an emulsion comprising a silicone phase and a phase comprising polypropylene glycol, as in claim 68.

Applicant's comments about a "three-component internal phase" are confusing. Powell et al. teach several embodiments of their composition, including one comprising an internal phase comprising polypropylene glycol (which is a hydrophilic carrier and a hydrophilic component) and an enzyme (which is both a hydrophilic component and an active agent) (column 15, line 67; and column 16, line 64, through column 17, line 5). Powell et al. teach that the internal phase may further comprise additional hydrophilic components, for example, ethanol (Example 13) and sodium chloride (Examples 22 and 23). In any case, the instant claims do not require three distinct components in the internal phase, since (like polypropylene glycol) a hydrophilic carrier is also a hydrophilic component. Indeed, in the instant specification, propylene glycol and polyethylene

glycol, and glycerin/glycerol are all exemplary embodiments both of "hydrophilic carriers" (page 8, lines 12-18) and "hydrophilic components" (page 9, lines 4-11). In short, claim 56 does not necessarily require that the internal phase comprise three distinct components.

Double Patenting

The double patenting rejections are withdrawn in light of applicant's comments.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

leb

SANDRA E. SAUCIER
PRIMARY EXAMINER